10 CT Calcium Automated Analysis

Introduction

The CT Calcium Automated Analysis application automatically highlights and quantifies coronary artery calcifications. The application estimates the coronary artery calcium category from non-cardiac-gated adult CT scans to support users with identifying subjects at increased cardiovascular risk, which can affect patient management.

To automatically detect calcification in the coronary arteries of patients in an opportunistic manner, processing in the Advanced Visualization Workspace is triggered automatically based on the preprocessing rules defined and based on the compatibility of the image with suitability criteria. The results are generated as Secondary Capture batches for suitable series identified as containing coronary calcification and sent to the configured PACS device(s).

Indications for Use

The CT Calcium Automated Analysis application is intended for use as a non-invasive post-processing software to evaluate calcified plaques in the coronary arteries, which indicate the presence of coronary artery disease.

The CT Calcium Automated Analysis device analyzes existing adult (>18 years) non-cardiac-gated CT studies. The device generates a 4-category output representing the estimated quantity of calcium detected together with preview axial images of the detected calcium meant for informational purposes only. The device output is available to the radiologist as part of their standard workflow. The CT Calcium Automated Analysis results are not intended to be used on a stand-alone basis for risk attribution, clinical decision-making or otherwise preclude clinical assessment of CT studies.

Intended Users

The CT Calcium Automated Analysis application is intended to be used by adequately trained and qualified medical professionals, including but not limited to physicians and medical technicians. The main clinicians or medical and para-medical professionals, who use the Philips Advanced Visualization Workspace application, are listed below:

- Radiologists in the radiology department/clinic
- 3D technologists in the radiology department

Intended Patient Population

The CT Calcium Automated Analysis application is intended to be used for scans from adults (18 years and above).

3000119307 61_A/881 * 2023-06-30

Benefits

When used as specified in the Intended Use, under the circumstances and conditions as specified in the Indications for Use, the CT Calcium Automated Analysis application assists the user in identifying patients at increased cardiovascular risk, which can affect patient management. The application allows the automatic detection and quantification of calcification in the coronary arteries of patients as an incidental finding.

Contraindications

- Results are not intended to be used on pediatric patients.
- Results are not intended to be used on a stand-alone basis for risk attribution, clinical decision-making or otherwise preclude clinical assessment of CT studies.

Key Features

The CT Calcium Automated Analysis application includes the following key features:

- Supports visualization of CT images.
- Provides a workflow that automatically sends the generated results to PACS or any other predefined destination.
- Provides configurable automatic results and preferences.
- Provides automatic data compliance and quality checks.
- Provides automatic detection, quantification and categorization (none/mild/moderate/severe) of coronary artery calcification.
- Provides results as secondary capture (CS) batch with a summary page, patient recommendations and pictorial segmentation of calcium specks.

3000119307 61_A/881 * 2023-06-30

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Limitations for Use

NOTICE

- The physician retains the ultimate responsibility for reporting an incidental finding of coronary calcium based on image visualization, as well as any segmentation and measurement results obtained from the application. CT Calcium Automated Analysis should not be used as the sole basis for clinical diagnosis. Users should review all outputs and findings.
- Results may not be optimal for patients with foreign bodies (e.g., stents, implants) or for patients post-CABG procedure.
- Incorrect DICOM headers or other factors can cause CT Calcium Automated Analysis to reject an input CT series for processing, in which case an output with a notification is generated.

WARNING

- **Verify calcium segmentation for Automatic Coronary Artery Calcification results.**
- **Calcium segmentation may be inaccurate, which may lead to inaccurate results.**
- **The system allows non-120 KVp scans. A warning is displayed in the results summary image of the batch:**

  Scan is not 120 KVp as recommended for Agatston scoring. This may impact the results.

300011930761_A/881 * 2023-06-30

Main User Workflow

Valid Studies for CT Calcium Automated Analysis

For optimal results in the CT Calcium Automated Analysis application, the following acquisition parameters are recommended:

- CT data only (non-gated and non-contrast). The application filters out spectral, decubitus and prone data.
- Slice thickness ≤ 3.2 mm
- Regular noise. The application excludes data with higher noise, which may be caused by e.g. low dose, obesity or artifacts.
- Axial image orientation. The application filters out non-axial data.
- Origina data. The application filters out non-original or derived/mixed data.

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CAUTION

The CT Calcium Automated Analysis AI algorithms were trained and evaluated with the data as specified in the intended data type. Using other acquisition parameters may lead to a rejected process or inaccurate results and should be avoided.

Intended Data Type

- Axial CT in Supine position
- Slice thickness ≤ 3.2 mm
- Original Primary/Original Secondary
- Non-contrast
- Non-gated
- Regular Noise (The application excludes data with a higher noise, which may be caused by e.g. low dose, obesity or artifacts).

Creation of CT Calcium Automated Analysis Results

Automatic Results Creation

It is possible to enable automatic results creation on the arrival of relevant data to Advanced Visualization Workspace.

Once relevant data (as configured in Preferences) arrives to Advanced Visualization Workspace, AVW recognizes the data as suitable for CT Calcium Automated Analysis Results creation. The Results are generated in the background and are auto-sent to the PACS device (as configured by the user). For configuration information, see section “Configuration of CT Automatic Coronary Artery Calcification Results” on page 318.

Manual Results Creation

It is also possible to activate the CT Auto Coronary Calcium creation manually, from the Patient Directory of Advanced Visualization Workspace.

Right click on the relevant series within the study and select: **Run Processing** > **CT Auto Coronary Calcium**.

The results are created for all selected series that match the criteria.

Configuration of CT Automatic Coronary Artery Calcification Results

To configure CT Auto Coronary Calcium Results:

1. Go to **Preferences** and select the **Viewing Applications** page.
2. Go to the **CT Automatic Coronary Calculation Results Creation for Chest CT** section and select the **Settings** button.

300011930761_A/881 * 2023-06-30

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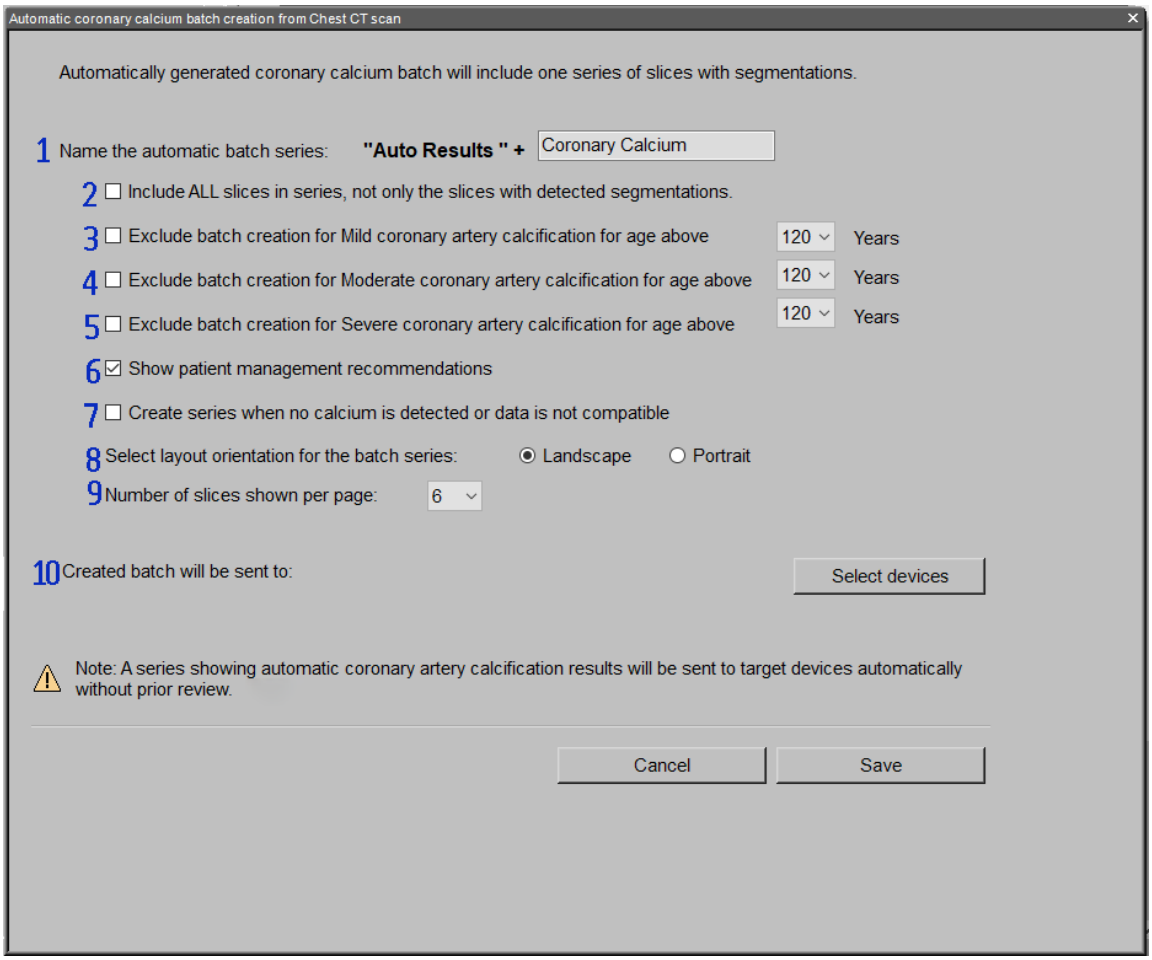
A configuration window is displayed.



3. Review the default settings and update as necessary.

1	**Name the automatic batch series "Auto-results" + Coronary Calcium**	The default name of the automatic result batch series description. It is possible to change the name in the text box.
2	**Include ALL slices in series, not only the slices with detected segmentations.**	When selected, all images are generated in the output batch. When this is not selected, only images with segmentations are generated in the output batch.
3	**Exclude batch creation for Mild coronary artery calcification for age above**	By default, the age to exclude is >120 years. The range available is 2- 120 years.
4	**Exclude batch creation for Moderate coronary artery calcification for age above**	
5	**Exclude batch creation for Severe coronary artery calcification for age above**	

3000119307 61_A/881 * 2023-06-30

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6	**Show patient management recommendations**	Checked by default. Controls the display of patient management recommendation in the summary page.
7	**Create series when no calcium is detected or data is not compatible**	This is not checked by default. When checked, the system generates a single image series with the message that no coronary calcium was detected. In case of incompatible data, a single image series with potential reasons for incompatibility is provided.
8	**Select layout orientation for the batch series**	Select either Landscape or Portrait.
9	**Number of slices shown per page**	Used to set the number of images shown in the tile view of the summary images. Default option is four for Landscape and six for Portrait orientation..
10	**Created batch will be sent to:**	Users can configure the destination device for automatic processing to a PACS destination/device.

NOTICE

A note informs users that unreviewed results are automatically sent to the configured target device.

A series showing automatic coronary artery calcification results will be sent to target devices automatically without prior review.

NOTICE

These preferences settings are system (site) specific and are not user specific.

To create processing rules:

1. Go to **Preferences** and select the **Processing** page.
2. Verify that **Enable Processing** is selected.
3. Verify that **Run processing according to the following** is selected.
4. Select the **Add** button.

   A new processing rule is added to the table.
5. In the **Algorithm** column (first column), select **CT Automatic Coronary Calculation Results Creation for Chest CT**

   The Configuration window opens. Close the window.
6. Fill in the relevant DICOM attributes for identification of the suitable series - Protocol, Body Part, series description, procedure description (this is a standard setting for all preprocessing algorithms).

300011930761_A/881 * 2023-06-30

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Results

Results are available in the Patient Directory with the prefix **Auto Results Coronary Calcium** and a suffix **Calcification detected** if Mild/Moderate/Severe calcification was detected.

CAUTION

Calcium segmentation may be inaccurate, which may lead to inaccurate results.

WARNING

Verify calcium segmentation for Automatic Coronary Artery Calcification results.

Results are in the Secondary Capture format.

Below is an example of the Summary Results page when KVp = 120.

The first image of the batch results displays a summary table with following details:

1 Score category indicated with a color for one of the categories (Mild, Moderate or Severe).

2 Result description and the patient management recommendations.

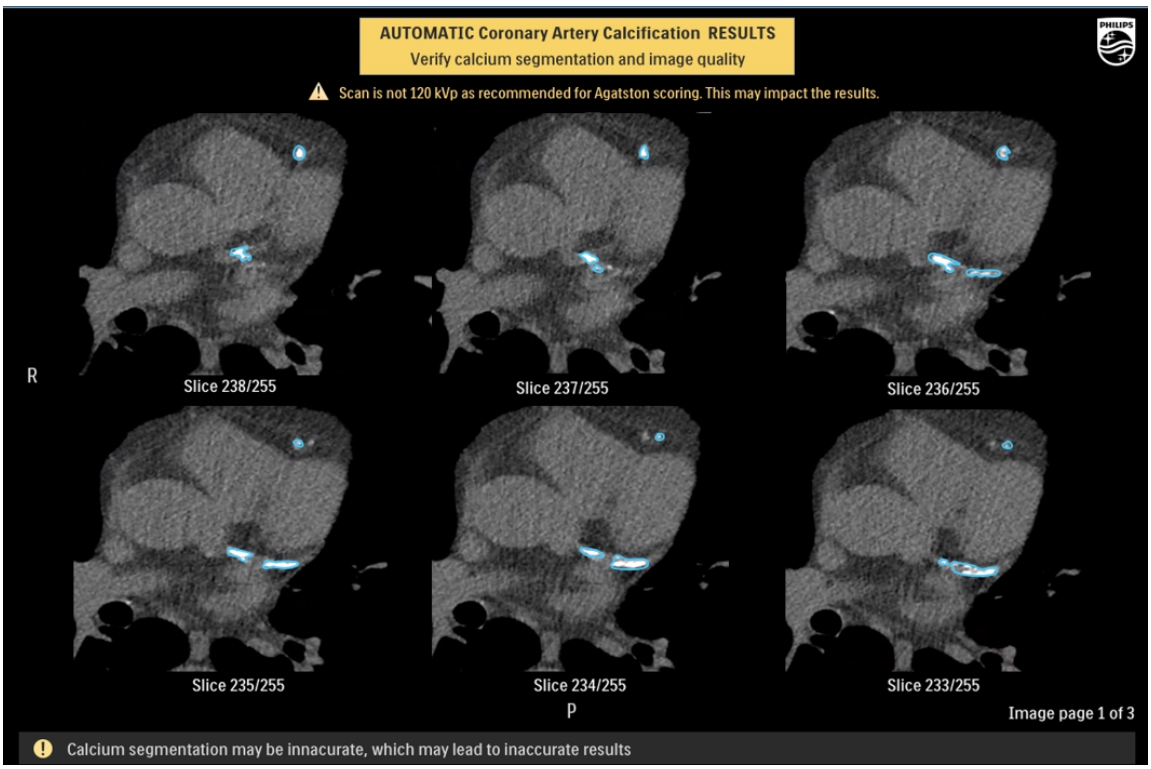
3 The reference details of the coronary calcification scoring and categorization and patient management recommendations.

In the background, the application measures the Agatston score based on the identified calcifications. The Agatston score is calculated according to Agatston et al.[1] and normalized to 3mm slice thickness. Based on the Agatston score, the application determines the category of coronary artery calcification severity according to Hecht et al.[2] and provides it on the summary page, as is visible in the above figure.

The next image displays tiled slices with calcium segmentation with highlighted contours around the detected calcium, without obscuring the calcium on the image.

The result summary page and all following pages of the SC display a warning when non-120KVp data is processed: **Scan is not 120 KVp as recommended for Agatston scoring. This may impact the results**.

Below is an example of the Summary Results page when KVp is not 120.



Results for Zero Calcification or Incompatible Scans

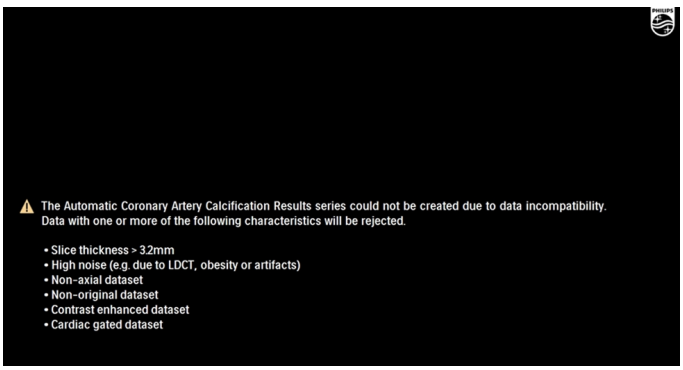
If no calcification is detected:

- If the checkbox for **Create series when no calcium is detected or data is not compatible** is checked, results content is created for failed cases and for data with no findings.

  The series name has the suffix **Zero Calcification**. For example, a complete series name would be "Auto Results Coronary Calcium – Zero Calcification " .

- For data with no findings, the series name has the suffix **Zero Calcification**. For example, a complete series name would be **Auto Results Coronary Calcium – Zero Calcification**. The following screen provides an example for Zero coronary artery calcification detected.

- For incompatible data, the series name is **Data Not Compatible for Auto Calcium Detection**. The following screen provides an example for data incompatibility.



References

1. Agatston AS, Janowitz WR, Hildner FJ, Zusmer NR, Viamonte M, Detrano R. Quantification of coronary artery calcium using ultrafast computed tomography. Journal of the American College of Cardiology. 1990 Mar 15;15(4):827–32.
2. Hecht HS, Blaha MJ, Kazerooni EA, Cury RC, Budoff M, Leipsic J, et al. CAC-DRS: Coronary Artery Calcium Data and Reporting System. An expert consensus document of the Society of Cardiovascular Computed Tomography (SCCT). Journal of Cardiovascular Computed Tomography. 2018 May 1;12(3):185–91.

Measurement Accuracy

The performance (measurement accuracy) of the CT CAA application can be measured as the agreement between the application's reported calcium category and the ground truth.

On a set of 436 patients (i.e. 298 lung cancer screening data from the US and 138 COVID-19 data from France) the found agreement in between the ground truth (provided by three US board certified physicians or relevant equivalent) CAC-DRS Category and the automatic CT CAA CAC-DRS Category is 0.84 (0.80-0.88) [Cohen's weighted kappa (95% Asymptotic Confidence Interval)].

300011930761_A/881 * 2023-06-30

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